UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/862,424	05/23/2001	Victor M. Markowitz	4010US (111944-0015)	8455

27189 7590 08/23/2005	EXAMINER
PROCOPIO, CORY, HARGREAVES & SAVITCH LLP	LY, CHEYNE D
530 B STREET	

	ART UNIT	PAPER NUMBER
SUITE 2100	2163	
SAN DIEGO, CA 92101		

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/862,424	MARKOWITZ, VICTOR M.
	Examiner	Art Unit	
	Cheyne D. Ly	2163	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _03 June 2005_.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1,16-21,24-28,35 and 37-41_ is/are pending in the application.

     4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _1,16-21,24-28,35 and 37-41_ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

     a)☐ All   b)☐ Some *   c)☐ None of:

         1.☐ Certified copies of the priority documents have been received.

         2.☐ Certified copies of the priority documents have been received in Application No. _____.

         3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

     * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The art unit designated for this application has changed. Applicants(s) are hereby informed that future correspondence should be directed to Art Unit 2163.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 03, 2005 has been entered.

3. Applicants' arguments, filed April 05, 2005, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

4. Applicant's argument "the final rejection is premature" has been responded to in the Advisory Action, mailed April 27, 2005.

5. Claims 1, 16-21, 24-28, 35, and 37-41 are examined on the merits.

CLAIM REJECTIONS - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 16-21, 24-28, 35, and 37-41 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ermolaeva et al. (1998).

RESPONSE TO ARGUMENTS

8. On pages 10-12, Applicant argues via Exhibit A that the "relational database of Ermolaeva et al. (ArrayDB) is a single database." Applicant's argument and Exhibit A have been fully considered, however, they are not persuasive because Exhibit A supports that the relational database of Ermolaeva et al. comprises "separate databases" as required by the instant specification. For example, a "relational database" has been cited via Exhibit A by Applicant to comprise related tables. Exhibit A describes "A table is a collection of records" (dictionary.net). Ramakrishnan R. (provided with the instant Office Action) describes "A database is a collection of data, typically describing the activities of one or more related organizations" (page 1). The American Heritage College Dictionary (provided with the instant Office Action) defines a database as "A collection of data arranged for ease of retrieval" (page 361). Further, Date C. J. (provided with the instant Office Action) describes a database comprising a single table (page 3, especially Figure 1.1). The Array DB Software Schema discloses the relational database comprising a plurality of separate tables, which have been reasonably construed as "[a] collection of data"; therefore, represents the required

"separate databases" as defined by Exhibit A, Ramakrishnan R., Date C. J., and The

American Heritage College Dictionary. The Array DB Software Schema of Ermolaeva et al.

reasonably represents the "separate databases" exemplified in Figure 7 of the instant

specification.

9. Specific to the amended limitation of "fragment index database", Ermolaeva et al.

disclose "Cl_id is an internal database indentifier. The 'Clone' field contains the IMAGE

clone identifier and is hyperlinked to the dbEST records containing the sequences of this

clone" (page 21, Figure 3) wherein the UniGene sequences in the dbEST database represent

"fragment index." Clone information stored in the ArrayDB is extracted from UniGene (for

example, sequence definition and accession number) (known standardized identifier). The

design accommodates addition of newly isolated clones for which accession numbers or

meaningful names are not yet available (unknown standardized identifier). ArrayDB

automatically scans a directory for new intensity data (expression level) (page 20, column 2,

last paragraph). The citation of Schuler G. (provided with the instant Office Action) is not

being used as prior, but only to expand on the inherent characteristics of the UniGene and

dbEST databases. Schuler G. describes the dbEST database comprising EST fragments of

about 400 bases (fragments) (Schuler G., page 694, column 3, line 1, to page 695, column 3,

line 11). The citation about reasonably anticipates the amended limitation as disclosed in the

instant specification (Figure 7, and pages 22 and 46).

10. Specific to the argument directed to the limitation of "clinical data", Applicant's argument

is not persuasive because the new limitation of "clinical data" is an optional limitation.

Therefore, claim 1, as a whole, does not overcome the instant prior art rejection with the amended limitation.

11. Specific to the "user query limitation", Ermolaeva et al. describes the Web-based user interface to the ArrayDB system that supports database queries and allows the retrieval of distinct types of information ranging from clone data to intensity data to analysis results." "ArrayDB supports database queries by different fields, such as clone ID, title, experiment number, sequence accession number…" ArrayDB provides hyperlinks to other databases such as dbEST, GenBank, UniGene, or KEGG (page 21, column 1, lines 5-16). As discussed above, the "clinical data" limitation is an optional limitation; therefore, it is not required for anticipation basis when Ermolaeva et al. has been cited to disclose the other optional limitations. Further, Applicant's argument "Ermolaeva et al. queries consisting of gene index and expression results alone" further supports that Ermolaeva et al. discloses the other optional limitations.

BASIS FOR REJECTION

12. Ermolaeva et al. discloses a method for data management and analysis of gene expression data from microarrays. The method of Ermolaeva et al. comprises the ArrayDB system wherein gene expression data is stored in a relational database (Abstract etc. and page 20, column 1, Box 1), as in instant claim 1, lines 1-5; claim 21, lines 1-6; and claim 35, lines 1-6.

13. Ermolaeva et al. discloses a complete relational schema of the database is available on request (Figure 2). The authors have provided the PTO a copy of the schema upon the

examiner's request. The citation of the Array DB Software Schema is not being used as prior

art, but only to expand on the inherent characteristics of said relational database. Further, the

limitation of "separate databases" has not been specifically defined in the instant

specification. Therefore, the relational database of Ermolaeva et al. comprising separate

tables (databases) is consistent with the required limitation. For example, the

adb_CALC_INTENSITY_99 relational table contains sample data (sample database),

UniGene and NonUniGene relational tables contain gene annotation data (annotation

database). "The relational database underlying the ArrayDB system stores extensive

information pertaining to each clone in the microarray, including a brief gene description,

GenBank accession number, IMAGE clone identifier" (page 20, column 2, lines 17-35).

Further, "[t]he 'clone' field contains IMAGE clone identifier and is hyperlinked to the

dbEST records containing the sequences of this clone" (page 21, Figure 3), as in instant

claim 1, lines 6-7 and 20-23; claim 21, lines 7-9 and 22-25; and claim 35, lines 1-8.

14. Clone information stored in the ArrayDB is extracted from UniGene (for example,

sequence definition and accession number) (known standardized identifier). However, the

design accommodates addition of newly isolated clones for which accession numbers or

meaningful names are not yet available (unknown standardized identifier). ArrayDB

automatically scans a directory for new intensity data (expression level) (page 20, column 2,

last paragraph). The disclosure of newly isolated clones has been reasonably construed as

sample data directed to genomics. The gene fragment classification cited above is consistent

with the disclosure for said classification in the instant specification (page 8, last paragraph).

Further, the gene fragments are grouped in to "only up-regulated clones or only down-regulated clones" (Figure 4), which represents "at least two gene fragment classes" based on expression results, as in instant claim 1, lines 8-19, claim 21, lines 10-21; and claim 35, lines 9-20.

15. The Web-based user interface to the ArrayDB system supports database queries which allows retrieval of distinct types of information ranging from clone data to intensity data to analysis results. "ArrayDB supports database queries by different fields, such as clone ID, title, experiment number, sequence accession number…" ArrayDB provides hyperlinks to other databases such as dbEST, GenBank, UniGene, or KEGG (page 21, column 1, lines 5-16). The queries generates results comprising expression data corresponding to the clones and intensity data which are displayed in the Multiexperiment viewer window (Figure 4), as in instant claim 1, lines 24-27; claim 21, lines 26-30; and claim 35, lines 20-25.

16. The ranking number is overlaid on the image for clones that have satisfied the query criteria wherein the ranking is according to ratio value. The ArrayViewer generates a cluster report (gene set). The MultipExperiment view supports analysis data from multiple experiments (across sample sets) (page 21, column 2, Data Analysis §, and Figure 3), as in instant claims 16, 24, and 37.

17. ArrayViewer comprises textboxes for specifying call value thresholds based on two fluorescent probes (pair) for identifying gene sets being present and absent within the sample

set as indicated by the "boxes" and ranking gene signature by ascending ratio value (pages

21-22, Data Analysis §, and Figure 3), as in instant claims 17, 25, and 38.

18. ArrayDB via the MultipExperiment (workspace manager) provides the comparison of

data over multiple experiments by comparing multiple samples of a particular type of tumour

or over a time course to determine differential expression. For example, the reference

(control) sample is cDNA prepared from yeast cells harvest at the first interval after

inoculation (page 23, column 1, lines 3-18). The control sample represents the first sample

set and the time course sample represents the second sample, as in instant claims 18, 19, 26,

27, and 39, and 40.

19. ArrayDB via the ArrayViewer allows users to select a range of expression ratios wherein

ArrayViewer returns information on genes with expression ratios in said range. Further, the

MultipExperiment returns clones with high or low ratios in an experimental series (page 22,

column 1, lines 15-18, and column 2, first paragraph), as in instant claims 20, 28, and 41.

CONCLUSION

20. Patent applicants with problems or questions regarding electronic images that can be

viewed in the Patent Application Information Retrieval system (PAIR) can now contact the

USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are

available to answer your questions daily from 6 am to midnight (EST). The toll free number

is (866) 217-9197. When calling please have your application serial or patent number, the

type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

21. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199. The USPTO's official fax number is (703) 872-9306.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

23. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SAFET METJAHIC, can be reached on (571) 272-4023.

C. Dune Ly
Patent Examiner
8/15/05

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